

510 (k) Summary

K070941
JUN 21 2007

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1. Submitter Information

Company name	TaiDoc Technology Corporation
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Date Prepared	Mar 30 th , 2007

2. Name of Device

Trade Names	Clever Chek Health Care System Software
Common Names	Data management software
Classification Names and Regulations	a) Calculator/data processing module for clinical use, Class I, 21CFR862.2100 b) Glucose Test System, Class II, 21CFR862.1345 c) Noninvasive Blood Pressure Measurement System, Class II, 21CFR870.1130,

3. Predicate Device

Trade/Proprietary Name:	Camit Diabetes Management Software
Common/Usual Name:	Data management software
Submitter	Roche Diagnostics Corporation
510 (k) Number	K001907

4. Device Description

The Clever Chek Health Care System Software is an optional software accessory for use with the following models with data management capabilities: a)Clever Chek blood glucose meters, b) Clever Chek blood glucose plus blood pressure monitors, and c) Clever blood pressure monitors. When use with one of these meters, Clever Chek Health Care System Software transfers data from the device's memory into a computer for enhanced data management.

5. Intended Use

The Clever Chek Health Care System Software is intended for use in home and clinical settings as an aid for people with diabetes and their health care professionals to review, analyze and evaluate the historical test results to support health management effectively.

6. Comparison to Predicate Device

The Clever Chek Health Care System Software is substantially equivalent to the Camit Diabetes Management Software (K001907). Both management software programs can be described as follows:

- have the same intended use.
- data transferred from the device cannot be changed or modified in any way.

7. Performance Studies

Testing of Clever Chek Health Care System Software included validation of hardware (data transfer through the cable) software and user evaluation. It demonstrated that the system meets its intended use.

8. Conclusion

Clever Chek Health Care System Software demonstrates satisfactory performance and is suitable for its intended use.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

TaiDoc Technology Corporation
c/o Ms. Erica (Pi-Shiou) Li
Management Representative
4F, No. 88, Sec. 1, Kwang-Fu Rd.
San-Chung, Taipei County
Taiwan 241

JUN 21 2007

Re: k070941
Trade/Device Name: Clever Chek Health Care System Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, DXN
Dated: March 30, 2007
Received: April 04, 2007

Dear Ms. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number: K070941

Device Name: Clever Chek Health Care System Software

Indications for Use:

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The Clever Chek Health Care System Software is intended for use in home and clinical settings as an aid for users and their health care professionals to review, analyze and evaluate the historical test results to support health management effectively.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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